biosimilar medicines

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Biosimilars Market Review

KEY FINDINGS

2025

Biosimilar medicines market review 2025

Key findings overview and policy recommendations

The Biosimilar Medicines Group Market Access Committee is pleased to present the **2025 Market Review: European Biosimilar Medicines Markets Policy overview**.

The purpose of this document is to provide a general overview of the policy frameworks and measures that are currently in place for biosimilar medicines in the different European countries allowing the reader to get a clear understanding.

The 2025 Market Review covers the following policy areas:

1. **Hospital tendering systems**
2. **Price adjustments**
3. **Budget control mechanisms**
4. **Governance and stakeholder engagement**

The European countries covered in this edition of the Biosimilar Medicines Market Review are: Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and Switzerland.

1. Hospital tendering systems

Design flaws threaten supply stability and fair competition

Key findings

Hospital tendering systems are in place in the vast majority of countries (26/29 countries), with a mix between national, regional and hospital (individual or group) level tenders, depending on the country

Tenders are mostly awarded based on the active substance (19 out of 26 countries), with few exceptions based instead on indications or on the individual brand.

Single-winner hospital tenders remain widespread, whereas multi-winner awards, while theoretically possible in many countries (11 out of 26 countries), seldom apply in practice. Even in cases where multi-winner tenders are applied, the volume distribution is not always applied, which defeats the intended positive effects this practice can have on diversification of supply and makes it challenging for companies to plan their production and supply.

In most cases, there is neither a minimum nor maximum volume foreseen in a tender. About 69% of countries (18/26) reporting no binding minimum or maximum volume in tenders. A further 27% (7/26) indicates a maximum volume, but only 11% (3/26) states a minimum volume.

Non-price criteria are rarely used or only in exceptional cases. Among 26 reporting countries, 54% (14/26) rely exclusively on price. 5 countries report non-price criteria being used in specific cases, while 7 report them being used in all cases. However, even in cases where non-price criteria are employed, the type of criteria differs significantly. Norway provides one of the few examples combining price, environment, and supply security factors, while the Netherlands and Belgium mention ESG, availability, or ease-of-use criteria. Nevertheless, in most cases price remains the decisive factor even when qualitative elements are included.

The lead time between the contract award and the first supply is often short with less than 60 days of contract signature in 69% of the countries (18/26). This means that in many cases, companies need to start biologic production without knowing whether they will be awarded the contract.

Industry is frequently not consulted during tender design. Half of the countries (13 out of 26) report that no formal consultation has taken place while 42% (11/26) describe some form of consultation, while Bulgaria notes that other stakeholders are consulted but not industry. (Q.46)

Central problem

Tenders based solely on price, with no foreseen volume commitments and no stakeholder dialogue, lead to unsustainable offers, discourage participation, and increase the risk of shortages.

As evidenced in IQVIA's report 'Assessing the biosimilar void', single source tenders are amongst the challenges that biosimilar development faces.[1]

Illustrative examples

In **Romania**, while the tender contracts foresee both minimum and maximum quantities, these are not enforced in practice.

In **Poland**, non-price criteria are always applied, however the most common one used is related to the terms of payment.

Policy recommendations

Public procurement plays a key role in medicines availability. To counterbalance existing problems, the upcoming revision of the Public Procurement Directive (2014/24/EU) needs to recognise the pharmaceutical sector as strategic and issue tailored rules in the form of a delegated act:

→ Mandating **MEAT** (Most Economically Advantageous Tender) award criteria to boost competition, as up to 84% of pharmaceutical contracts rely solely on price.

→ Prioritising **multi-winner tenders** to enable healthy competition strengthen supply security and prevent shortages.

→ Allowing **price adjustments** to address inflation and economic shifts.

→ Reinforcing **investigations** of **abnormally low bids** by establishing clear assessment criteria for contracting authorities in Article 69 of the public procurement directive.

Positive case studies

Norway shifted from a winner-takes-all approach , multi-winner tenders to address market consolidation. In Norway, MEAT criteria are always incorporated into tender design. The predefined weighting allocates 25% to price, 30% to environmental considerations, and the remaining percentage to factors such as supply and available stocks. Moreover, the lead time from the signature of the contract until the first supply is six to nine months and the industry and trade association (Farma Norge) has also opportunities to give feedback when the tender is being designed, making sure that the interests of the biosimilar medicines industry are being considered in the process.

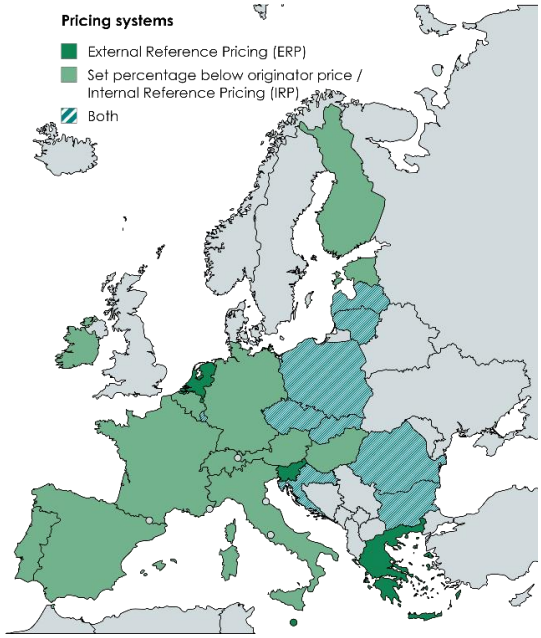
[1] IQVIA, Assessing the biosimilar void (October 2023).

2. Price adjustments

Lack of upward flexibility

Key findings

Almost all European countries (86% or 25/29 countries) operate under regulated pricing systems for biosimilar medicines. Only 4 countries (Denmark, Sweden, the United Kingdom and Malta) have free pricing frameworks in place, however, in these countries different measures are in place to control the acquisition costs of biosimilar medicines through e.g. procurement.



Most commonly European countries set the price of biosimilar medicines below a specific percentage from the price of the originator (19 countries) or by external reference pricing (13 countries). These two mechanisms are sometimes used in combination, as is the case in many CEE (Central and Eastern European) countries.

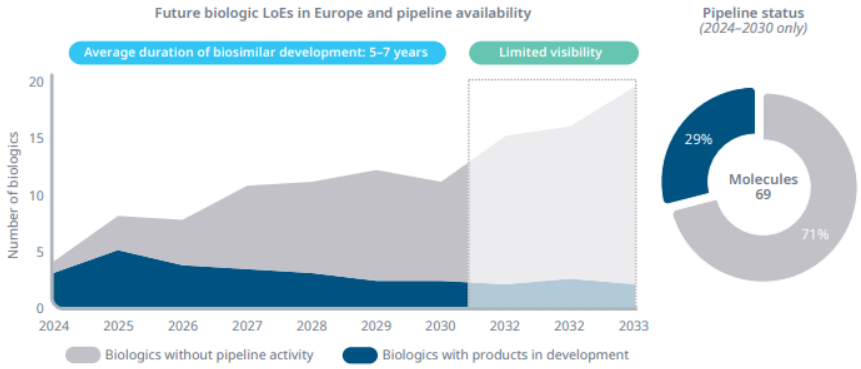
Price adjustments for biosimilar medicines occur on average every six months to a year. In the majority of responding countries, prices are only adjusted downwards. While in general, frameworks do not prohibit increases, they rarely happen in practice. For example a couple of countries report measures implemented in recent years to respond to inflation, however these mostly remain one-time only or done on an exceptional basis.

Central problem

Biosimilar competition in Europe has been crucial in driving both healthcare savings (cumulating to €56 Bn, as of July 2024) and expansion of patient access to treatment, providing nearly 7 billion patient treatment days (cumulated, as of July 2024) in Europe since the first biosimilar approval in 2006. [2]

[2] https://www.iqvia.com/-/media/iqvia/pdfs/library/white-papers/the-impact-of-biosimilar-competition-in-europe-2024.pdf

Exhibit 5: Biologics at risk of no, or limited, competition (molecules, 2024–2030)



Source: IQVIA Patent Intelligence (2024); IQVIA analysis of the IQVIA Global Biosimilar Database (Q3 2024).

Notes: Timeframe is limited to 2030 (low pipeline potential >7 years into the future due to the biosimilar development timeline); Global pipeline analysis includes all biosimilars in development from pre-clinical pre-registered; excl. approvals. To reduce uncertainty in pipeline forecast data, data from 2024 onwards is shown as a 3-year rolling average. The IP profile of individual biologics is subject to change as new patents and/or patent extensions become available during a product lifecycle. The data shown in this chart is accurate as of November 2024.

However, existing dysfunctions in the market, including in how pricing and reimbursement policy measures are applied and combined, play a role in discouraging further investment in biosimilar candidate development, in turn affecting the number of competitors entering the market. As illustrated in the graph, out of 69 molecules losing exclusivity by 2030, only 29% of them have biosimilars in development, leading to a huge loss of opportunity. [2]

Illustrative examples

In **Slovakia**, ERP is directly applied to biosimilars, with the price being determined based on average of the three lowest EU prices (basket all EU countries). While price increases are theoretically possible under the external reference pricing system, however, in practice, this does not happen cannot be raised, even when the average of the three lowest EU prices (basket all EU countries) exceeds the Slovak drug price. This acts as a disincentive for companies to launch their product in the country.

Policy recommendations

P&R policy measures play a key role in market policy frameworks for biosimilar markets. In order to ensure a sustainable market which appeals to biosimilar medicines suppliers and encourages competition, the following measures should be considered:

→ Establish a **simplified arithmetic adjustment mechanism** triggered by objective cost indicators like inflation, energy, transport, workforce cost trends, which include built-in safeguards to mitigate anti-competitive effects and inflationary pressures.

→ **Exclude biosimilar medicines** from **External Reference Pricing** (ERP), in line with EURIPID guidelines [3] which recommend its application to medicines without competition

→ Allow **upward price revisions** on a duly justified basis based on transparent criteria (e.g., inflation index, input cost escalation, risk of discontinuation).

[3] Assessment report of the degree of ERP implementation at the country level, prepared by Agency for Health Technology Assessment and Tariff System (AOTMiT) Attachment_0.pdf

Positive case studies

Bulgaria has introduced a regulatory mechanism allowing for an annual adjustment of the maximum price of all medicinal products, including originator and biosimilar medicines, based on the average annual inflation rate. This update follows the Regulation on the Conditions, Rules, and Procedure for Regulating and Registering the Prices of Medicinal Products (SG, issue 28 of 2021). As a subordinate piece of legislation (Ordinance), it supplements the Law on Medicinal Products in Human Medicine, which does not specifically address inflation but instead lays out fundamental principles for determining maximum medicinal product prices. This positive change resulted from continuous efforts of the off-patent industry, primarily in response to the COVID-19 pandemic. Most importantly, under this regulation, the Marketing Authorization Holder (MAH) must submit an application to adjust the price in line with the average annual inflation rate. The National Council for Prices and Reimbursement of Medicinal Products then conducts an External Price Reference (ERP)as of the application date, aligns the price accordingly, and subsequently increases it to reflect.

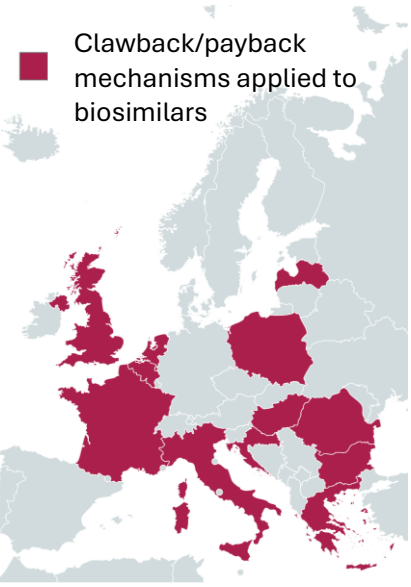
3. Budget control mechanisms

Excessive burden on biosimilar medicines suppliers

Key findings

Clawback/Payback mechanisms and mandatory rebates are in place in a significant number of countries, alongside other budgetary control mechanisms. Clawback/payback mechanisms are applied to biosimilar medicines in 12/29 countries.

There is no differentiated clawback for biosimilar medicines in comparison to originators, with the only exceptions being the UK, where the clawback mecanism also considers the level of reduction from the originator product pre-loss of exclusivity, and Romania where different caps are applied for innovative medicines versus biosimilar and generic medicines.



Budget overruns are in many cases paid back by the pharmaceutical industry, which cover 50 – 100% of the value exceeded.

Industry involvement in budgetary planning is limited or absent in most cases. In terms of process, a majority of internal survey respondents noted that there was no formal feedback mechanism and indicated limited or absent formal involvement of companies in budget planning. In a few instances, the industry had been consulted through feedback sessions.

Central problem

Biosimilar medicines have generated €56 billion in cumulative savings for European healthcare systems, including €16 billion over 2023-2024 alone.[2] However, blanket cost-containment policies that fail to distinguish biosimilar medicines from originator medicines unfairly burden biosimilar suppliers, which already contribute to the sustainability of the health system through the savings they offer.

Illustrative examples

In **Bulgaria**, a clawback mechanism is applied to all reimbursed medicinal products, originator, generic and biosimilar medicines, without differentiation. It is based on the

comparison between actual pharmaceutical expenditure and target spending thresholds, which are defined by quarterly and annual budget ceilings across five therapeutic groups and adjusted in line with the actual growth rate relative to the previous year. When expenditure exceeds these targets, marketing authorisation holders are required to repay to 100% of the overspend. The mechanism ensures full recovery of excess spending, is implemented uniformly across all product types, and is subject to annual reconciliation procedures.

Policy recommendations

- → Implement **clawback exemptions** or **lower rates** for biosimilar medicines taking into account the dynamic competition and ensuing savings they already bring to the system.
- → Implement **segmented budget caps**, differentiated between on- and off-patent medicinal products, in order to better assess overspend in each category.
- → Replace rigid, one-size-fits-all mandatory discounts with **flexible policies** that evaluate each product's market conditions (e.g., market size, competitive landscape, margin structure) on a **case-by-case basis**. This approach maintains savings while ensuring market sustainability and patient access.
- → Ensure transparent clawback methodologies and allow **stakeholder participation** in their design.

Positive case studies

In **Romania** clawback was capped and differentiated between innovative and biosimilar medicines, with 25% applying to innovative medicines and 15% biosimilars.

4. Governance and stakeholder engagement

Systemic underrepresentation

Key findings

Few countries have formal, regular mechanisms for industry input on budgetary decisions, pricing frameworks, or tender designs.

Where consultations occur, they are often non-binding or limited to public comment without feedback loops.

Central problem

Effective pharmaceutical policy requires predictable, transparent engagement. Current gaps reduce policy efficiency and increase risks of unintended consequences.

Illustrative examples

In **Belgium**, Medaxes, the trade association representing the off-patent pharmaceutical industry, is not a member of the General Council, however, the originator association has a seat at the table, which leads to an imbalance in representation leading to policy making.

Policy recommendations

→ To uphold evidence-based and transparent decision-making, pharmaceutical budget allocation, pricing frameworks, and tender designs must undergo a comprehensive consultation process before being adopted. This process should actively engage the off-patent industry allowing them to provide valuable feedback. Without such engagement, the off-patent sector would lack the opportunity to present crucial considerations, such as industry-specific challenges and manufacturing or supply chain complexities, which are essential for ensuring timely and reliable medicine availability.

Positive case studies

Italy implemented thorough feedback processes for hospital tender design and pharmaceutical budget decision-making, incorporating mechanisms ranging from

public consultations to dedicated industry feedback sessions. These structured engagements ensured transparency, fostered stakeholder participation, and facilitated evidence-based policymaking.

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